REMARKS

Claims 1, 2, 4-11, 13-19, and 21-48 are pending. Claims 5-10, 14-19, 21-26, 29, 30, 32, 33, 36, 37, and 45-48 have been withdrawn as being drawn to non-elected inventions or species. Withdrawn claim 37 has been amended to correct an inadvertent error in claim format. Claim 44 has been amended to correct an editorial error. Thus, no new matter is added by the present amendments. Claims 1, 2, 4, 11, 13, 27, 28, 31, 34, 35, and 38-44 are under consideration.

The Sequence Listing has been amended to remove sequences that were inadvertently included, but are not disclosed in the specification. In particular, the sequences for SEQ ID NOs: 384, 385, 387 and 388 have been removed and replaced with the code "000" to indicate that no sequence is present for the respective sequence identifier.

Also, paragraph 110 of the substitute Specification filed on November 14, 2004 has been amended to correct an inadvertent typographical error in sequence identifier. In particular, the wrong sequence identifier *i.e.*, SEQ ID NO:376, was recited for the sequence YMDGTMSQV—GSG—HWDFAWPW. The specification has been amended to recite the correct sequence identifier, *i.e.*, SEQ ID NO:373.

Thus, no new matter is added.

Claims

The Examiner states that new claim 48 is withdrawn from consideration as being directed to a non-elected species. Upon the allowance of a generic claim, Applicants request the Examiner's consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. Presently, Applicants believe that claims 4, 13, 38, 42-44, and 48 within Group I are generic with respect to the species of heat shock proteins.

The Examiner also states that a complete reply to the final Office Action mailed April 18, 2007 must include cancellation of nonelected claims or other appropriate action.

Applicants point out that withdrawn process claims 5-10, 14-19, 21-26, and 45-47 are still pending, since Applicants believe that process claims 5-10, 14-19, 21-26 and 45-47, which include all the limitations of a pending product claim under consideration (*i.e.*, product claim within elected Group I), are eligible to be rejoined upon the allowance of a product claim in accordance with the provisions of M.P.E.P. § 821.04.

Applicants also point out that claims 29, 30, 32, 33, 36, 37 and 48, which are withdrawn as being drawn to non-elected species, are still pending, since Applicants believe that claims 29, 30, 32, 33, 36, 37 and 48 should be considered upon the allowance of a generic claim as provided by 37 C.F.R. § 1.141.

Inventorship

Applicants respectfully request that the Examiner consider and grant the Request to Correct Inventorship under 37 C.F.R. § 1.48(a) submitted concurrently herewith to delete Jessica B. Flechtner, Kenya Prince-Cohane, Sofija Andjelic, and Brian H. Barber as co-inventors of the subject matter claimed in the above-identified patent application, in order to correctly name Paul Slusarewicz and Sunil Mehta as the only true co-inventors.

THE REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN

The Examiner maintained the rejection of claims 1, 2, 4, 11, 13, 27, 28, 31, 34, 35, and 38-44 under 35 U.S.C. § 102(e) as being anticipated by Wieland et al., U.S. Patent Application Publication No. 2004/0071656 ("Wieland et al."), which is the publication of U.S. Patent Application No. 10/328,953 ("the Wieland application"), filed on December 23, 2002. The Wieland application claims benefit, *inter alia*, of a provisional application filed on December 26, 2001. In the Office Action of September 21, 2006, the Examiner contends that Wieland et al. teaches a composition of a heat shock protein non-covalently linked to an antigen via a polypeptide that can be used in inducing an immune response in a mammal, and that one of the polypeptides listed is homologous to SEQ ID NO:417 (NLLRLTGW) of the claimed invention. Further, the Examiner states that Wieland et al. discloses infectious disease antigens such as herpes virus that can be non-covalently linked to a heat shock protein such as hsc70, which can also function as an adjuvant.

In response, Applicants submit that claims 1, 2, 4, 11, 13, 27, 28, 31, 34, 35, and 38-44 are not anticipated by Wieland et al. for the reasons set forth below.

The legal test for anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in

possession of the invention. *W.L. Gore Associates v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983); *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985).

However, an applicant's own work, even though publicly disclosed prior to his application, may not be used against him as a reference, absent the existence of a time bar to his application. *In re DeBaun*, 687 F.2d 459, 462 (C.C.P.A. 1982) (citing *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982)).

The Manual of Patent Examining Procedure (M.P.E.P.) § 2136.05 provides that a 35 U.S.C. § 102(e) rejection can be overcome by submitting an affidavit or declaration under 37 CFR § 1.132 establishing that the relevant disclosure is applicant's own work:

> [I]f applicant's work was publicly disclosed prior to his or her application, applicant's own work may not be used against him or her unless there is a time bar under 35 U.S.C. 102(b). *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)). Therefore, when the unclaimed subject matter of a reference is applicant's own invention, applicant may overcome a *prima facie* case based on the patent, ** U.S. patent application publication>,< or international application publication, by showing that the disclosure is a description of applicant's own previous work. Such a showing can be made by proving that the patentee, or ** the inventor(s) of the U.S. patent application publication or the international application publication, was associated with applicant (*e.g.* worked for the same company) and learned of applicant's invention from applicant. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969).

(M.P.E.P. § 2136.05 at 2100-97 (8th ed., Rev. 5, Aug. 2006)).

In *In re DeBaun*, 687 F.2d 459 (C.C.P.A. 1982), the Court of Customs and Patent Appeals held that a prior art rejection based on a patent could be overcome by the filing of a declaration under 37 C.F.R. § 1.132 by the inventor and applicant of the application under prosecution, Kenneth W. DeBaun, showing that the subject matter disclosed in the cited patent was DeBaun's own invention. In the declaration, DeBaun stated that insofar as the invention of his application is suggested by anything contained in the cited patent, it was originally conceived by him and described to patent counsel prior to the filing date of the cited patent for purposes of preparing a patent application, which resulted in the cited patent. *Id.* at 462. The other patentees need not submit an affidavit disclaiming inventorship. *In re DeBaun*, 687 F.2d 459 (C.C.P.A. 1982); M.P.E.P. § 2136.05 at 2100-98.

Further, the M.P.E.P. § 2136.05 at 2100-98 (8th ed., Rev. 5, Aug. 2006) provides that "when the reference reflects applicant's own work, applicant need not prove diligence or

reduction to practice to establish that he or she invented the subject matter disclosed in the reference."

The claims of the instant application are directed to a hybrid antigen comprising at least one antigenic domain of an infectious agent or tumor antigen and a binding domain that non-covalently binds to a heat shock protein, optionally with a peptide linker separating the antigenic domain and binding domain, wherein the binding domain comprises the amino acid sequence Asn Leu Leu Arg Leu Thr Gly Trp ("NLLRLTGW"), Phe Tyr Gln Leu Ala Leu Thr Trp ("FYQLALTW"), or Arg Lys Leu Phe Phe Asn Leu Arg Trp ("RKLFFNLRW"); compositions comprising at least one such hybrid antigen and a pharmaceutically acceptable carrier; compositions comprising a non-covalent complex of at least one such hybrid antigen and at least one heat shock protein; and methods of inducing an immune response to a tumor antigen or an infectious agent or methods of treating an infectious disease or cancer comprising administering at least one such hybrid antigen, optionally non-covalently bound to at least one heat shock protein.

Wieland et al. discloses a complex of a heat shock protein and a hybrid antigen comprising an antigenic domain, a heat shock protein binding domain, and optionally a short peptide linker interposed therebetween (*see* Wieland et al. at ¶20). In particular, the heat shock protein binding domain can comprise the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW (*see* Wieland et al. at ¶¶129-130).

Applicants state that the disclosure in Wieland et al. relating to a complex of a heat shock protein and a hybrid antigen comprising an antigenic domain, a heat shock protein binding domain, and optionally a short peptide linker interposed therebetween, wherein the heat shock protein binding domain can comprise the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW was derived from the inventors of the presently claimed subject matter, and is a disclosure of Applicants' invention. The Examiner's attention is invited to the Declaration of the Inventors under 37 C.F.R. § 1.132 ("the Inventors' Declaration")[1] and the Declaration of Michael A. Yamin, Ph.D. under 37 C.F.R. § 1.132 ("the Yamin Declaration") submitted herewith, which clearly evidence that the relevant disclosure

[1] The Inventors' Declaration was executed by Drs. Paul Slusarewicz and Sunil Mehta on October 2, 2007 and January 15, 2008, respectively. Applicants note that Dr. Mehta's curriculum vitae (Exhibit 2 of the Inventors' Declaration) had not been updated to reflect his recent change in residence address and employment. Dr. Mehta's updated residence and employment are, however, recited in paragraph 2 of the Inventors' Declaration executed by Dr. Mehta. The Inventors' Declaration executed by Dr. Mehta differs from the Inventors' Declaration executed by Dr. Slusarewicz only in paragraph 2.

in Wieland et al. of a complex of a heat shock protein and a hybrid antigen comprising an antigenic domain, a heat shock protein binding domain, and optionally a short peptide linker interposed therebetween, wherein the heat shock protein binding domain can comprise the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW is Applicants' own invention. Briefly, the Inventors' Declaration and the Yamin Declaration demonstrate that (i) such invention was originally conceived by inventors Drs. Paul Slusarewicz and Sunil Mehta and disclosed by Dr. Mehta to Dr. Michael A. Yamin prior to December 26, 2001; (ii) Dr. Yamin used the disclosure of Dr. Mehta, *inter alia*, to prepare the instant application and provisional applications to which the instant application claims priority; and (iii) Dr. Yamin used the disclosure of Dr. Mehta to incorporate the idea of using peptides having the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW as a heat shock protein binding domain to generate hybrid antigens non-covalently complexed to heat shock proteins into the specification of U.S. Provisional Application No. 60/414,834 filed on September 28, 2002, to which the Wieland application claims priority and, subsequently, into the specification of the Wieland application.

In the Inventors' Declaration, the inventors Drs. Slusarewicz and Mehta state that insofar as the claimed invention of the instant application is suggested or disclosed by anything contained in Wieland et al., such invention was originally conceived by them and disclosed by Dr. Mehta to Dr. Yamin prior to December 26, 2001 (see the Inventors Declaration at ¶¶ 3, 9-18).

As evidence of Drs. Slusarewicz and Mehta's conception prior to December 26, 2001 of the claimed invention of the instant application of a hybrid antigen containing the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW, optionally containing a peptide linker, and optionally complexed non-covalently to a heat shock protein and uses of such hybrid antigens or non-covalent complexes, the Inventors' Declaration (¶¶ 9-17) and Exhibits 3-6 thereof are presented.

Drs. Slusarewicz and Mehta state that the documents entitled "Certificate of Analysis" presented in Exhibit 3 of the Inventors' Declaration:

> disclose the amino acid sequences NLLRLTGW, FYQLALTW, and RKLFFNLRW of the heat shock protein binding peptides designated SJAV1, SJAV2, and SJAV3, respectively. These peptides were ordered for members of our research group from New England Peptide, Inc. The documents contain quality control test results for each of the SJAV1 (NLLRLTGW), SJAV2 (FYQLALTW), and SJAV3 (RKLFFNLRW) peptides supplied by New England Peptide, Inc.

(see the Inventors' Declaration at ¶ 10).

With respect to Exhibit 4 of the Inventors' Declaration, Drs. Slusarewicz and Mehta state that:

> Exhibit 4 contains notebook pages 57-58 of Notebook No. 44 issued to Irina Kostareva. Although the date on the pages of Exhibit 4 has been blanked-out, such date is prior to December 26, 2001. Exhibit 4 documents the conjugation of the antigen ovalbumin ("OVA") to the heat shock protein binding domain SJAV1 (NLLRLTGW) peptide or "Jav-G-S-G" peptide to generate a hybrid antigen. The Jav-G-S-G peptide has a heat shock protein binding domain followed by the GSG peptide linker. Irina Kostareva was an employee of Mojave, who reported to Paul Slusarewicz. The experiments documented in the notebook pages of Exhibit 4 were carried out by Irina Kostareva under the supervision of Paul Slusarewicz.

(see the Inventors' Declaration at ¶ 11).

With respect to Exhibit 5 of the Inventors' Declaration, Drs. Slusarewicz and Mehta state that:

> Exhibit 5 contains notebook pages 73-75 of Notebook No. 44 issued to Irina Kostareva. Although the date on the pages of Exhibit 5 has been blanked-out, such date is prior to December 26, 2001. Exhibit 5 documents the conjugation of OVA to the heat shock protein binding domain SJAV2 (FYQLALTW) peptide (referred to as "SJ2" in Exhibit 5). The experiments documented in the notebook pages of Exhibit 5 were carried out by Irina Kostareva under the supervision of Paul Slusarewicz.

(see the Inventors' Declaration at ¶ 13).

With respect to Exhibit 6 of the Inventors' Declaration containing an e-mail from Dr. Mehta to Dr. Yamin, Drs. Slusarewicz and Mehta state that:

> Although the date of the e-mail has been blanked-out, such date is prior to December 26, 2001. This e-mail documents the disclosure of our invention to Michael A. Yamin for purposes of preparing U.S. Provisional Application No. 60/447,142 filed on February 13, 2003 and subsequently the '521 application [the instant application] and its other priority applications. The e-mail discloses the amino acid sequences, dissociation constants ("Kds") for binding to Hsp70, heat shock proteins the peptides are disclosed to bind to (in the respective listed publications), and other related information for the peptides S-Jav1 (NLLRLTGW), S-Jav2 (FYQLALTW), and S-Jav3 (RKLFFNLRW), which were conceived by us for use in generating hybrid antigens.

(see the Inventors' Declaration at ¶ 16). The Inventors' Declaration serves as evidence that the amino acid sequences NLLRLTGW, FYQLALTW, and RKLFFNLRW as heat shock protein binding peptides for use in covalent conjugation, optionally via a peptide linker, to an

antigen to generate a hybrid antigen, optionally complexed non-covalently to heat shock protein, as well as the uses of such hybrid antigens and complexes in methods of inducing an immune response to a tumor antigen or an infectious agent or methods of treating an infectious disease or cancer, as originally conceived by Drs. Slusarewicz and Mehta, were disclosed to Dr. Yamin at a time prior to December 26, 2001 for purposes of preparing the instant application and its priority applications (see the Inventors' Declaration at ¶¶ 16-17).

In the Yamin Declaration, Dr. Yamin confirms the exchange of information between him and Dr. Mehta:

> The amino acid sequences NLLRLTGW, FYQLALTW, and RKLFFNLRW as heat shock protein binding peptides for use in covalent conjugation, optionally via a peptide linker, to an antigen to generate a hybrid antigen, optionally complexed non-covalently to heat shock protein, as well as the uses of such hybrid antigens and complexes in methods of inducing an immune response to a tumor antigen or an infectious agent or methods of treating an infectious disease or cancer were disclosed to me by Dr. Sunil Mehta prior to December 26, 2001, for purposes of preparing U.S. Provisional Application No. 60/447,142 filed on February 13, 2003, and subsequently the '521 application and its other priority applications. As evidence of this disclosure, attached hereto as Exhibit 2 is a copy of an e-mail from Dr. Sunil Mehta to me disclosing the amino acid sequences, dissociation constants ("Kds") for binding to Hsp70, heat shock proteins the peptides are disclosed to bind to (in the respective listed publications), and other related information for the peptides S-Jav1 (NLLRLTGW), S-Jav2 (FYQLALTW), and S-Jav3 (RKLFFNLRW), which were for use in generating hybrid antigens. Although the date of the e-mail has been blanked-out, such date is prior to December 26, 2001.

(see the Yamin Declaration at ¶ 12).

Dr. Yamin further states that he "used the information in Exhibit 2 along with other disclosures provided by Dr. Paul Slusarewicz and other members of Dr. Slusarewicz's research group to prepare provisional applications to which the '521 application claims priority, and subsequently the '521 application, with the assistance of outside patent counsel" (see the Yamin Declaration at ¶ 13).

Dr. Yamin also states that since he was involved in preparing the Wieland application and the provisional applications to which the Wieland application claims priority; he:

> incorporated the idea of using peptides having the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW as a heat shock protein binding domain to generate hybrid antigens non-covalently complexed to heat shock proteins into the specification of U.S. Provisional Application No. 60/414,834 filed on September 28, 2002 and subsequently into the specification of the Wieland application.

(see the Yamin Declaration at ¶ 14).

December 26, 2001 is the earliest priority date to which the Wieland application claims priority. However, the first disclosure of a complex of a heat shock protein and a hybrid antigen comprising an antigenic domain, a heat shock protein binding domain, and optionally a short peptide linker interposed therebetween, wherein the heat shock protein binding domain can comprise the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW is found in U.S. Provisional Application No. 60/414,834 filed on September 28, 2002, to which the Wieland application claims priority.

Dr. Yamin further states that he was involved in establishing a research collaboration between (a) Mojave, and (b) Drs. Felix Wieland and Franz-Ulrich Hartl (the inventors of the Wieland application) and members of their research groups:

> I also was involved in establishing a plan for a research collaboration ("the Collaboration") in 2002 between (a) Mojave, and (b) Drs. Felix Wieland and Franz-Ulrich Hartl (the inventors of the Wieland application) and members of their research groups. In furtherance of the Collaboration, it was intended that Mojave supply its collaborators with peptides with high affinity binding to Hsp70.

(see the Yamin Declaration at ¶ 15).

Exhibit 3 in the Yamin Declaration serves as additional evidence to document one occasion prior to September 28, 2002 that information relating to the claimed invention of the instant application was disclosed by Dr. Yamin to a member of Dr. Felix Wieland's research team (Dr. Wieland is an inventor of the Wieland application) under a confidentiality agreement in the context of the potential research collaboration:

> Attached hereto as Exhibit 3, is a copy of my handwritten note which evidenced that I disclosed the NLLRLTGW amino acid sequence of the S-Javl peptide to Thalia Becker, a Ph.D. student of Dr. Felix Wieland at the time and one of the Mojave collaborators of the Collaboration. This disclosure was pursuant to a confidentiality agreement. Although the date on the handwritten note has been blanked out, such date is prior to September 28, 2002. Exhibit 3 serves as evidence of an occasion prior to September 28, 2002 when I communicated the idea of using peptides having the amino acid sequence NLLRLTGW as a heat shock protein binding domain to generate hybrid antigens non-covalently complexed to heat shock proteins as described and claimed in the '521 application to a member of Dr. Wieland's research team.

(see the Yamin Declaration at ¶ 16). Thus, the Yamin Declaration demonstrates how information regarding the claimed invention of the instant application was (i) transmitted from Dr. Mehta to Dr. Yamin; (ii) transmitted to a member of Dr. Wieland's research team;

and (iii) incorporated into the Wieland application and U.S. Provisional Application No. 60/414,834 filed on September 28, 2002, to which the Wieland application claims priority.

In the Yamin Declaration, Dr. Yamin states that:

> I (i) disclosed the idea of using peptides having the amino acid sequence NLLRLTGW as a heat shock protein binding domain to generate hybrid antigens non-covalently complexed to heat shock proteins as described and claimed in the '521 application to Thalia Becker, a Ph.D. student of Dr. Wieland; and (ii) incorporated into the specification of U.S. Provisional Application No. 60/414,834 filed on September 28, 2002 and subsequently into the specification of the Wieland application the disclosure of using peptides having the amino acid sequence NLLRLTGW, FYQLALTW, or RKLFFNLRW as a heat shock protein binding domain to generate hybrid antigens non-covalently complexed to heat shock proteins, as described and claimed in the '521 application.
>
> Insofar as the invention of the pending '521 application is suggested or disclosed by anything contained in Wieland et al., such invention was (i) described to me by Dr. Sunil Metha prior to December 26, 2001; (ii) disclosed to the inventors of the Wieland application, Drs. Felix Wieland and Franz-Ulrich Hartl, or a member of their research teams prior to September 28, 2002 by me; and (iii) incorporated by me into the specification of U.S. Provisional Application No. 60/414,834 filed on September 28, 2002 and subsequently into the specification of the Wieland application.

(see the Yamin Declaration at ¶¶ 17-18).

In view of the foregoing, Applicants submit that the relevant disclosure in Wieland et al., which is the basis of the Examiner's rejection of the claimed invention of the instant application, is actually a disclosure of Applicants' own invention, as conceived by Applicants and transmitted to Dr. Yamin prior to December 26, 2001, and incorporated into Wieland et al. by Dr. Yamin. Thus, Wieland et al. is not prior art to the instant application, and claims 1, 2, 4, 11, 13, 27, 28, 31, 34, 35, and 38-44 are not anticipated by Wieland. Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

CONCLUSION

Applicants respectfully request that the above amendments and remarks be entered and made of record in the file history of the instant application.

Respectfully submitted,

Date: January 18, 2008

Adriane M. Antler 32,605

Adriane M. Antler (Reg. No.)
JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3939